

**Package leaflet: Information for the user**  
**Ethambutol 100 mg & 400 mg Film-coated Tablets**

ethambutol hydrochloride

The name of this medicine is Ethambutol 100 mg & 400 mg Film-coated Tablets which will be referred to as Ethambutol Tablets throughout this leaflet.

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Ethambutol Tablet is and what it is used for
2. What you need to know before you take Ethambutol Tablets
3. How to take Ethambutol Tablets
4. Possible side effects
5. How to store Ethambutol Tablets
6. Contents of the pack and other information

**1. What Ethambutol Tablet is and what it is used for**

The active ingredient in your tablets is ethambutol hydrochloride, which belongs to a group of medicines called anti-tuberculosis drugs. These are used to treat and prevent tuberculosis which is an infectious disease mainly affecting the lungs.

**2. What you need to know before you take Ethambutol Tablets**

**Do not take Ethambutol Tablets if you:**

- **are allergic** to ethambutol, or any of the **other ingredients of this medicine** (listed in section 6)
- have problems with your eyes or your eyesight (unless your doctor has decided it is essential)
- have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking ethambutol.

**Warnings and precautions:**

Talk to your doctor or pharmacist before taking Ethambutol Tablets if you:

- have **problems with your eyesight** - your doctor will arrange for a full check of your eyesight before you start taking this medicine. If you notice any changes to your vision whilst taking this medicine, you should stop taking the tablets and inform your doctor immediately. In the majority of cases, any changes to vision will return to normal within a few weeks/ months after stopping treatment however, in rare cases it may take longer for eyesight to recover or the change may become permanent
- have a history of kidney problems. Before treatment with ethambutol tablets you should have your kidneys checked, as your doctor may decide to adjust the dose of Ethambutol Tablets.
- develop symptoms suggestive of hepatitis (e.g., abdominal pain, fever, loss of appetite) or feel generally unwell, you may need your liver functions tested.

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Serious skin reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN) and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Ethambutol treatment. Stop taking Ethambutol and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

**Other medicines and Ethambutol Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription.

You should not take ethambutol tablets at the same time as antacid medicine containing aluminium hydroxide (used to treat heartburn and indigestion) as this can make ethambutol less effective.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

Ethambutol occasionally cause sight problems and numbness, dizziness, disorientation or paraesthesia (abnormal sensation like pins and needles) of the furthest parts of your body and disorientation. After taking your medicine you should not drive or use machinery, until you know how ethambutol effect you.

**Ethambutol Tablets contains sodium**

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take Ethambutol Tablets**

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

- The tablets should be taken once daily.
- They should be swallowed whole with a drink of water, do not chew or crush the tablets.
- The dosage of this medicine varies from person to person depending on your age, how much you weigh and whether it is being used for the treatment or for the prevention of tuberculosis.
- Patients who have kidney problems may need blood tests so that their doctor can reduce the dose in some cases.
- If you are not sure how many tablets to take, or when to take them, ask your pharmacist.

**Adults:**

- *Prevention and first time treatment:* The usual dose of ethambutol for adults for prevention of tuberculosis or for first time treatment for tuberculosis is 15 mg per kg of body weight per day.
- *Second time (or subsequent) treatment:* The usual dose of ethambutol for adults for second time (or subsequent) treatment of tuberculosis is 25 mg per kg of body weight per day for the first 60 days, reducing to 15 mg per kg of body weight per day for as long as the doctor considers necessary.

**Children:**

- *Prevention:* The usual dose of ethambutol for children for prevention of tuberculosis is 15 mg per kg of body weight per day.
- *First time, second time (or subsequent) treatment:* The usual dose of ethambutol for children for first time treatment, second time treatment or subsequent treatment of tuberculosis is 25 mg per kg of body weight per day for the first 60 days, reducing to 15 mg per kg of body weight per day for as long as the doctor considers necessary

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**Elderly:**

The same dosages as for adults are usually used although reduced doses may be required in older people who have kidney problems; in these patients the doctor will carry out blood tests to determine the dose required.

**If you take more Ethambutol Tablets than you should**

If you have taken an overdose of this medicine (that is more than the doctor has told you to) and experience symptoms like gastrointestinal disturbances, vomiting, fever, headache, anorexia, dizziness, hallucination and /or visual disturbances, get medical help immediately, either by calling your doctor or going to the nearest hospital casualty department. Remember to take the labelled medicine bottle with you, whether there are any Ethambutol Tablets left or not.

**If you forget to take Ethambutol Tablets**

If you forget to take a tablet you should take it as soon as you remember. However, if this is within 2 hours of your next dose you should skip the missed tablet and carry on taking the rest of your tablets as usual.

Do not take a double dose to make up for the forgotten dose.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

**Stop using Ethambutol and tell your doctor immediately if you notice any of the following:**

- severe allergic reaction known as an anaphylactoid reaction, which is characterised by difficulty in breathing, a flushed appearance, agitation or an irregular heartbeat
- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis)
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome)
- yellowing of the skin or whites of the eyes caused by liver or blood problems (Jaundice).

**If you notice any changes or problems with your sight, contact your doctor immediately.**

**Uncommon (may affect up to 1 in 100 people)**

- Ethambutol has occasionally caused sight problem. In this majority of cases these will return to normal after stopping treatment. However in rare circumstances, the problem may take longer to heal or become permanent.
- Ethambutol can cause hyperuricaemia, a condition similar to gout.

**Rare (may affect up to 1 in 1000 people)**

- Ethambutol can cause muscle weakness and wasting, pain, numbness, pins and needles sensations, rashes, itching, and hives.
- thrombocytopenia (which may result in bruising, nosebleeds, pinpoint red spots, prolonged bleeding after injury)

**Very rare (may affect up to 1 in 10,000 people)**

- Ethambutol can cause, blood disorders like leucopenia and neutropenia; allergic reactions, pins or swelling of joints, headache, dizziness, mental confusion, disorientation, hallucinations, generally feeling unwell, shortness of breath, chest pains, blisters or peeling, blistering following exposure to sunlight, kidney problems (lower back pain, pain or burning when passing urine, difficulty passing urine)

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- Other unwanted effects include loss of appetite, feeling sick, being sick, stomach pain and upsets

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help more information on the safety of this medicine.

**5. How to store Ethambutol Tablets**

Keep this medicine out of the sight and reach of children.

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the pack after 'Exp'. The expiry date refers to the last day of that month.

Do not throw any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

**6. Contents of the pack and other information****What Ethambutol Tablets contains**

- The active substance is ethambutol hydrochloride.
- 100mg: Each film-coated tablet contains 100 mg of ethambutol hydrochloride
- 400mg: Each film-coated tablet contains 400 mg of ethambutol hydrochloride
- The other ingredients are sodium starch glycolate, maize starch, povidone, colloidal anhydrous silica, microcrystalline cellulose, magnesium stearate and colours containing polydextrose, hypromellose, titanium dioxide (E171), macrogol and yellow iron oxide (E172); the 400 mg tablets also contain black iron oxide (E172).

**What Ethambutol Tablets looks like and contents of the pack**

Ethambutol 100 mg Film-coated Tablets are yellow, round, film coated tablets.

Ethambutol 400 mg Film-coated Tablets are grey, round, film coated tablets.

Ethambutol Tablets are available in Al/PVC/PE/PVDC blisters and PP tablet containers. Each pack contains 56 tablets.

**Marketing Authorisation Holder:**

Dawa Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD, United Kingdom

**Manufacturer:**

Drugsrus Ltd, 5 Sandridge Close, Harrow, Middlesex, HA1 1XD, United Kingdom

**This leaflet was last revised in 07/2024.**

**Blind or partially sighted?**

**Is this leaflet hard to see or read?**

**Call 020 8423 2111 to obtain the leaflet in a format suitable for you.**

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